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HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-7195			MARX, IRENE	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/05 has been entered.

Claims 1-3, 9-12, 14, 20-21 and 26 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 9-12, 14, 20-21 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing that there is no clear indication as to the nature of the materials in the prior art that wish to be excluded by the recitation of "consisting essentially of" particularly in the context of a composition using the open language "comprising", which does not limit the composition to the components specifically recited. Thus, the claim as written are at least ambiguous as to what is intended.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also Atlas Powder Co. v.

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E.I. duPont de Nemours & Co. , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama - Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.").

Claim 1 is vague, indefinite and confusing in the recitation of "industrially prepared" regarding a triglyceride comprised by the composition. The commercial sources of the composition disclosed in the Specification as filed do not indicate the sources of the triglycerides recited with any particularity, such that it cannot be assessed whether the triglycerides in fact are "industrially prepared" or extracted from natural sources. No details as to the components are provided. See, e.g., specification, page 8. The preparations designated MCTG 1 and 2 are not identified as to method of "industrial preparation" or extraction from natural sources or as to their distinguishing properties.

Claim 1 is confusing in the use of the singular "triglyceride" to denote what appears to be a mixture of triglycerides. Or is one triglyceride intended?

In addition the amount of "ppm" for the enzyme is confusing in Claim 1. Generally enzymes are characterized by units of activity rather than by concentration.

Claim 14 fails to find proper antecedent basis in claim 1 for "said triglyceride". Claim 1 is directed to "industrially prepared triglyceride."

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. A feed composition generally is intended for animals. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8-11 and 20-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by breast milk from humans and other animals as evidenced by Tang *et al.*, and Hurley for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to nutritional composition comprising about 0.25 to about 10% triglyceride 12 medium chain fatty acids and at least one active lipolytic enzyme, comprising about 0.25 to about 10 % triglyceride and about 100 to about 10,000 ppm lipolytic enzyme wherein the triglyceride consists essentially of C₆ to C₁₀ fatty acids.

Breast milk contains about 4% triglycerides as evidenced by Hurley and naturally contains about 100 ppm (0.1 mg/ml) of active bile-salt activated lipase among the lipases in the composition. Inasmuch as the claims as written are directed to a composition comprising industrially prepared triglycerides which consist essentially of certain fatty acids, the nature of other triglycerides and/or fatty acids that are in the nutritional composition cannot be readily ascertained. The nature of other triglycerides and/or fatty acids comprised by the nutritional

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composition is not set forth with any particularity. Therefore, the breast milk from humans and other mammals appears to anticipate the claimed composition.

In addition, the mode of preparation of a triglyceride does not alter the intrinsic properties thereof. A medium chain triglyceride prepared "industrially" is chemically indistinguishable from a naturally produced medium chain triglyceride, and applicant has not demonstrated otherwise. Regarding the alleged benefits of specific concentrations and ratios, they do not pertain to the invention as claimed.

The source of triglycerides is not seen as distinguishing the composition. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

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applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Relying on Table 1, page 10 of the instant specification applicant alleges that industrially prepared triglycerides "MCTG 1" and "MCTG 2" contain much higher concentrations of C8 and C10 fatty acids compared to naturally occurring triglycerides, such as butterfat and coconut oil. This may be so. However, the rejection is not made over butterfat or coconut oil

In addition, there is no substantiation by appropriate evidence on the present record that that "MCTG 1" and "MCTG 2" are, in fact, industrially prepared or how, and by whom. The fact that a preparation is sold, does not make it industrially prepared. In addition, the arguments are directed to a preparation consisting of 69.1% of C₈ fatty acids and 27.7% of C₁₀ fatty acids, and overall 99.6% of C₆ to C₁₀ medium chain fatty acids or a composition consisting of 57.5% of C₈ fatty acids and 42.3% of C₁₀ fatty acids, and overall 100% of C₆ to C₁₀ medium chain fatty acids. Yet, the claims are directed to a feed composition **comprising** about 0.25 to about 10% industrially prepared triglyceride and about 100 to about 10,000 ppm active lipolytic enzyme, for use as a medicament, wherein said industrially prepared triglyceride consists essentially of C₆-C₁₀ medium chain fatty acids.

There is no clear correlation between the arguments and the claim designated invention. Applicant appears to misinterprets the principle that claims are interpreted in the light of the specification. In this case, the elements of "industrially prepared triglycerides" in certain ratios are not clearly and explicitly found as examples or embodiments in the specification. In this case, also, the specific ratios are not claimed explicitly. Nor were the words that are used in the claims defined in the specification to require these limitations. A reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give meaning to disputed terms. The claims as written are directed to a composition comprising industrially prepared triglycerides which consist essentially of certain fatty acids. The claims do

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not clearly indicate the nature of other triglycerides and/or fatty acids that are in the nutritional composition.

Moreover, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In *re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In *re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or component would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

As noted *supra*, in the instant case, there is no clear indication as to the materials in the prior art that wish to be excluded by the recitation of "consisting essentially of" particularly in the context of a composition using the open language "comprising", which does not limit the

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composition to the components specifically recited. Thus, the claims as written are at least ambiguous as to what is or is not included or excluded from the feed composition.

Moreover, and more importantly, applicant has not demonstrated with objective evidence a patentable distinction between the composition as claimed and human or other breast milk from any mammal.

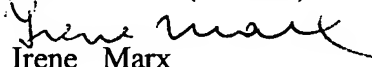
The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' composition differs and, if so, to what extent, from the compositions produced by humans and other mammals. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Therefore the rejection is deemed proper and it is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
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